PSJ1 Exh 6

From: Raub, Philip
Sent: Mon, 21 Nov 2016 16:23:48 -0500
To: Doerr, Mark;Zakin, Adam;Jenson, Jill;Chunderlik, George;Carryer, Lisa;Hughes, Nathan
Subject: RE: Suspicious Order Monitoring (SOM)
Attachments: Project Scope - Drug Control Program - 11 21 2016.doc

Scope Document attached. We will review during tomorrows call.

Thank you,

Phil

-----Original Appointment-----
From: Doerr, Mark
Sent: Wednesday, November 16, 2016 11:58 AM
To: Doerr, Mark; Zakin, Adam; Jenson, Jill; Chunderlik, George; Carryer, Lisa; Hughes, Nathan; Raub, Philip
Subject: Suspicious Order Monitoring (SOM)
When: Tuesday, November 22, 2016 4:00 PM-5:00 PM (UTC-05:00) Eastern Time (US & Canada).
Where: dial in # below

Chairperson - Mark

Ready Access
1-800-868-7719
Chairperson/Moderator Passcode: 5676
Participant Passcode/7-digit Access Code: 9674612

Objectives:

- Get me up to speed on status
- Outline Plan of Action
- Timeline for implementation

Project Scope

Drug Control Program

Project Manager: Jill Jenson
Business Analyst: Phil Raub

Revision History

Date	Contributor	Modifications Made
11.18.16	Phil Raub	Initial Draft
11.21.16	Phil Raub	Update

Glossary

Term	Definition
GERx / GERxDC	Giant Eagle Pharmacy Distribution Center and CII Warehouse
GE	Giant Eagle
DEA	Drug Enforcement Agency
CII	DEA classification. Narcotics.
CII-CV	DEA classification. Non-narcotic, but increased controls
CFR	Code of Federal Regulations
CSOS	Controlled Substance Ordering System
SL	SupplyLogix

Approval and Authority to Proceed

The Scope Document is used to define the boundaries of the project. It is a written agreement between the project team and the person(s) that commissioned and sponsored the project. The Scope Document provides the basis for future project decisions and must accurately reflect any revisions that are made to the scope of the project. After decisions have been made around solution design, any changes to scope will result in a Project Change Request.

Name	Title	Department	Signature	Date
Mark Doerr	Sr. VP Pharmacy	Pharmacy		

1.0 Stakeholders

1.1. Project Sponsor

- Mark Doerr – Senior Vice President Pharmacy

1.2. Project Decision Makers

- Adam Zakin – Sr. Dr, Pharmacy Administration
- Mike Chappel – Director, Pharmacy Operations
- Lisa Carryer – Director, Pharmacy Technologies
- Bob McClune – Sr. Category Mgr, Pharmacy
- George Chunderlik – Manager, Pharmacy Compliance
- Joe Lazzaro – Sr. Manager, Pharmacy Applications

1.3. Project Stakeholders

- Pharmacy Administration
- Pharmacy Operations
- Pharmacy Technologies
- Pharmacy Loss Prevention

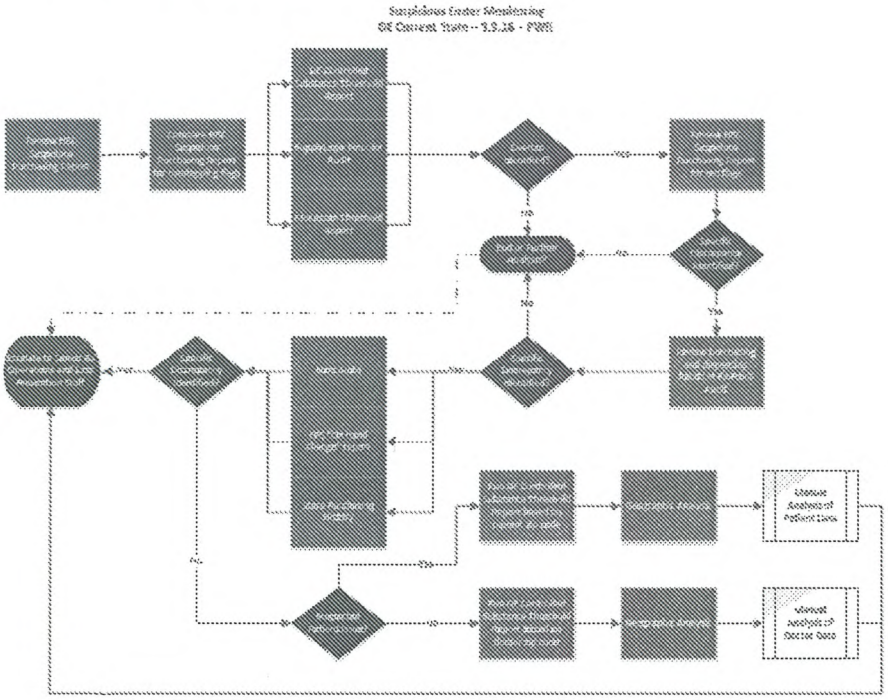
2.0 Project Scope Statement

Prior to January 2016, Giant Eagle's (GE) drug control program was limited to the monitoring of store based dispensing of schedule II (CII) narcotics. GE's primary and secondary suppliers of CII products were responsible for the monitoring of orders from distribution centers to GE retail pharmacies. With the completion of the GE CII warehouse (GERx) came the need for a more robust monitoring program that covers store to patient as well as distribution center to store transactions.

DEA Regulation CFR 1301.74(b), specifically requires that a registrant "design and operate a system to disclose to the registrant suspicious orders of controlled substances." Purposefully vague, the DEA leaves GE (the registrant) to interpret the elements and metrics of a monitoring system. It is the belief of the business that Giant Eagle's suspicious order monitoring is 75 to 85 percent of where it needs to be. The missing 15 to 25 percent of the necessary functionality needed to bring Giant Eagle into full compliance with CFR 1301.74(b) can be achieved through the following:

- *Dynamic Threshold Management*
- *Reengineering and formalizing the current investigative process*
- *The implementation of a case management process.*

2.1. Current Condition:



- Utilizing exiting reports and tools the operations team, led by the compliance manager, identifies potential issues through heavy manual analysis.
- The current state utilizes a static threshold that is established across all stores by product. This threshold changes monthly.
- No formal case management or tracking process is in place.

2.2. Target Condition

- Dynamic threshold management - Through the use of the current Anda CSOS tool, GE will be able to set thresholds at the chemical level on a quarterly basis. The tool will provide GE with the ability to block orders that exceed the set threshold and notify a user(s) when an order approaches the established threshold.
- Reengineering and formalizing the current investigative process - With the establishment of dynamic thresholds comes the opportunity to reengineer the investigative process. Review the capabilities of existing SupplyLogix (SL) tools and outline how to utilize PinPoint Audit and Monitor more effectively.
- The implementation of a case management process – The absence of a formalized case management tool/process is a visible gap. While the SupplyLogix (SL) case management module falls short of GE requirements, this project will bridge the gap between SL and a robust case management process that is secure and effective.

3.0 Business Case

3.1. Strategic Alignment

- ❖ Aligns with the FY16 Key Initiative:
  - Contract Compliance and order management: improve compliance with SupplyLogix applications with a focus on CIIs.

3.2. Roadmap Alignment

- ❖ Aligns with the Pharmacy Strategic Map:
  - Operational Excellence
  - Profitable Growth

3.3. Capability Alignment

- ❖ Operate (Core) - Manage Products/Lifecycle-Customer/Team Member Experience

3.4. Tangible Benefits and Measurement Plan

- ❖ Continue to maintain and operate a CII warehouse and dispense CII products at GE retail stores by compliance with CFR 1301.74(b)

3.5. Intangible Benefits

- ❖ Improved Customer Service

4.0 Business Risks/Constraints/Dependencies/Assumptions

- ❖ Business Risks
  - Lost Profitability, should the DEA find GE is out of compliance with CFR 1301.74(b)
    - Shutdown of GERx CII warehouse
    - Higher product costs
    - Customer disruption
- ❖ Constraints
  - Current financial and resource constraints
- ❖ Dependencies
  - The dynamic threshold management requirements can be accommodated by existing Anda CSOS functionality.
- ❖ Assumptions
  - If dynamic threshold management requirements cannot be accommodated by existing Anda CSOS functionality, development of the necessary functionality would be necessary within GE-DOS.

5.0 Vision and Solution

This project will establish a formalized drug control program, driven by the requirements for GE to be compliant with CFR 1301.74(b). The drug control program will focus on three key areas: (1.) the reengineering and formalization of the current investigative process; (2.) the creation of

a dynamic threshold management tool; and (3.) the implementation of a formalized case management process.

5.1. Re-use of Existing Technology

- Anda CSOS Application
  - If this will not suit GE requirements, GE-DOS would be considered
- SupplyLogix Tools
- Existing GE Reporting

5.2. Open Source Technology Considered/Third Party Solutions

- Anda CSOS Application
- SupplyLogix Audit and Monitor

5.3. Innovative Technology

- NA

5.4. Impact on Support Resources

- Corporate Users will need trained

5.5. Cost Justification for Use of Paper/Print

- NA

6.0 Scope Inclusions

- Dynamic Threshold Management for CII products
  - Primarily – Utilization of the Anda CSOS tool
  - Secondary – If primary is not feasible, internal development supporting the ordering and monitoring of CII products in GE-DOS.
- Reengineering and Formalizing the current investigative process
  - Utilizing existing application and reporting - minimize internal report development.
- The implementation of a case management process.

7.0 Scope Exclusions

- Threshold management for non-CII products (CIII to CV)
- Custom development around the SupplyLogix case management tool

8.0 Implementation Approach

- Requirements & Design: Nov 28 – Dec 30
- Development: Jan 2 – Jan 20
- QA Testing: Jan 23 – Feb 3
- Training: Feb 6
- Deployment: Feb 7 – Feb 17

9.0 Deliverables and Acceptance Criteria

Deliverables	Acceptance Criteria	Responsible

10.0 Recommendations for Future Phases

- Inclusion of CIII to CV controlled pharmaceutical products in all aspects of the drug control program, specifically threshold management.